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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/831,879	05/22/2001	Kazuya Katagai	MUR-026-USA-	8324
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27955	7590	11/16/2005
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MINNEAPOLIS, MN 55402

EXAMINER
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GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/831,879

Applicant(s)

KATAGAI ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 13 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Receipt of Amendments and Remarks filed on 9/8/05 is acknowledged. Claims **1 and 8** are pending in this application. Claim 13 is withdrawn as being directed to a non-elected invention.

#### *Withdrawn Rejections*

1) The rejection of claims 1, 8, 11-13, and 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments of 9/8/05.

2) The rejection of claims 1, 8, 11-12, and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Oda et al (5,725,874) in view of Linkwitz et al (6,295,469) is withdrawn in view of the amendments of 9/8/05. In particular, example 35 wherein sodium hydrogen and oxyquinoline sulfate is in a weight ratio of 30:1 and example 36 wherein sodium hydrogen and oxyquinoline sulfate is in a weight ratio of 60:1, respectively, demonstrate that sodium hydrogen and oxyquinoline sulfate in the above weight ratio provides stability to the gel composition comprising lidocaine and epinephrine over time.

3) The rejection of claims 1, 8, 12, and 17 under 35 U.S.C. 103(a) as being unpatentable over Oda et al (5,725,874) in view of Lugnani et al (5,843,016) is withdrawn in view of the amendments of 9/8/05. In particular, example 35 wherein sodium hydrogen and oxyquinoline sulfate is in a weight ratio of 30:1 and example 36 wherein sodium hydrogen and oxyquinoline sulfate is in a weight ratio of 60:1, respectively, demonstrate that sodium hydrogen and oxyquinoline sulfate in the above weight ratio provides stability to the gel composition comprising lidocaine and epinephrine over time.

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4) The rejection of claim 11 under 35 U.S.C. 103(a) as being unpatentable over Oda et al (5,725,874) in view of Lugnani et al (5,843,016) in further view of JP 08-325149 is withdrawn in view of the amendments of 9/8/05. In particular, example 35 wherein sodium hydrogen and oxyquinoline sulfate is in a weight ratio of 30:1 and example 36 wherein sodium hydrogen and oxyquinoline sulfate is in a weight ratio of 60:1, respectively, demonstrate that sodium hydrogen and oxyquinoline sulfate in the above weight ratio provides stability to the gel composition comprising lidocaine and epinephrine over time.

*New Rejection Necessitated by the Amendment of 9/8/05*

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 1 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.**

Applicant has amended the claims to recite "sodium hydrogen sulfite and oxyquinoline sulfate in a total weight ratio of 30:1 to 60:1 as antioxidants" which does not have support in the specification as originally filed. The examiner notes that that example 35 provides support for the weight ratio of 30:1 and example 36 provides support for the weight ratio of 60:1

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respectively; however the specification does not provide for support for the range *within* this range, 30:1 to 60:1. The examiner suggests amending the claim to recite 30:1 or 60:1 to overcome this rejection.

### ***Conclusion***

All the claims are rejected at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi  
Examiner  
Art Unit 1616



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER